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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

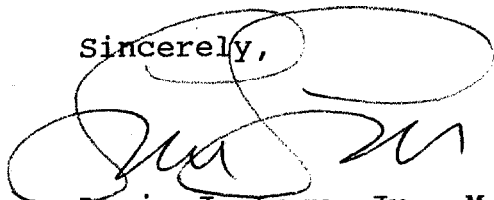
RE: Docket No. **97N-484S**

To Whom It May Concern:

It has been brought to my attention that there is a proposed FDA regulation that would regulate some types of allograft as medical devices. It has been my experience as a practicing physician using allograft extensively in my surgical practice that the present regulations covering the use of tissue allograft materials has been more than satisfactory to satisfy the safety of these materials. These tissues are hard enough to come by and create a huge expense for the patients as things stand. The addition of further layers of federal bureaucracy that Docket No. **97N-484S** would involve would only escalate the costs of these grafts, putting them out of the reach of many patients, and greatly curtailing the supply of these tissues that need to be available on a moment's notice. I feel that pursuing this form of regulation would be overtly harmful to the general public and would merely add another layer of bureaucracy rather than provide any true value or protection.

I would like to make my opinion heard that I am strongly against these proposed regulations.

Sincerely,



Louis J. Levy, Jr., M.D.

LJL:klm

97N-484S

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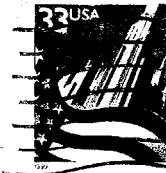
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